CLEAN VERSION OF CLAIMS

1. A method of preventing the formation of inhibitory antibodies to a protein delivered to a mammal by way of gene therapy, said method comprising administering to said mammal an immunosuppressive agent in conjunction with said gene therapy, said gene encoding the delivered protein being the same species as said mammal.

2. The method of claim 1, wherein said mammal and gene are human.

3. The method of claim 1, wherein said gene therapy is delivery of a nucleic acid encoding Factor IX to said mammal, which when expressed in said mammal, serves to produce a beneficial effect in said mammal.

4. The method of claim 1, wherein said delivered protein is selected from the group consisting of Factor VII, Factor VIII, Factor IX, Factor X, alphalantitrypsinogen, glucuronidase, a sarcoglycan, an interferon, insulin-like growth factor, and erythopoietin.

5. The method of claim 1, wherein said gene therapy is delivery of Factor IX to said mammal.

6. The method of claim 1, wherein said gene therapy is performed by administering a viral vector to said mammal, wherein said viral vector comprises a nucleic acid to be delivered to said mammal.

7. The method of claim 6, wherein said viral vector is an adeno-associated viral vector.

8. The method of claim 5, wherein said Factor IX is delivered to said mammal using an adeno-associated virus vector.

9. The method of claim 1, wherein said immunosuppressive agent is selected from the group consisting of cyclophosphamide, FK506, anti-CD40 ligand, CTLA4Ig, cyclosporin, antiB71-B72, and an immunosuppressive steroid.

10. The method of claim 9, wherein said immunosuppressive agent is cyclophosphamide.

12. The method of claim 1, wherein said mammal has hemophilia B and said inhibitory antibodies specifically bind with Factor IX protein.

13. A method of reducing formation of an inhibitory antibody to a protein delivered to a mammal by way of gene therapy, said method comprising administering to said mammal an immunosuppressive agent in conjunction with said gene therapy, said gene encoding the delivered protein being the same species as said mammal.

14. The method of claim 13, wherein said mammal and gene are human.

15. The method of claim 13, wherein said gene therapy is delivery of a nucleic acid encoding Factor IX to said mammal, which when expressed in said mammal, serves to produce a beneficial effect in said mammal.

16. The method of claim 13, wherein said delivered protein is selected from the group consisting of Factor VII, Factor VIII, Factor IX, Factor X, alphalantitrypsinogen, glucuronidase, a sarcoglycan, an interferon, insulin-like growth factor, and erythopoietin.

17. The method of claim 13, wherein said gene therapy is delivery of Factor IX to said mammal.

18. The method of claim 13, wherein said gene therapy is performed by administering a viral vector to said mammal, wherein said viral vector comprises a nucleic acid to be delivered to said human.

19. The method of claim 18, wherein said viral vector is an adeno-associated viral vector.

20. The method of claim 17, wherein said Factor IX is delivered to said mammal using an adeno-associated virus vector.

21. The method of claim 13, wherein said immunosuppressive agent is selected from the group consisting of cyclophosphamide, FK506, anti-CD40 ligand, CTLA4Ig, cyclosporin, antiB71-B72, and an immunosuppressive steroid.

22. The method of claim 21, wherein said immunosuppressive agent is cyclophosphamide.

23. The method of claim 13, wherein said mammal has hemophilia B and said inhibitory antibody specifically binds with Factor IX protein.

24. The method of claim 1, wherein said mammal has no detectable endogenous expression of said gene.

25. The method of claim 13, wherein said mammal has no detectable endogenous expression of said gene.

26. The method of claim 1, wherein said immunosuppressive agent is administered prior to, concomitantly with or following said gene therapy.

27. The method of claim 13, wherein said immunosuppressive agent is administered prior to, concomitantly with or following said gene therapy.

28. The method of claim 1, wherein said immunosuppressive agent is administered concomitantly with said gene therapy.

29. The method of claim 13, wherein said immunosuppressive agent is administered concomitantly with said gene therapy.